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Original 510(k)  
Tiodized® Screw (Slotted, and Internally and Externally Hexed)

Section 6

letterhead

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.  
Submitter's Address: 22895 Eastpark Drive  
Yorba Linda, CA 92887  
U.S.A.  
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Steri-Oss Inc.  
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Date Prepared: November 1996

Device Name:

Common Name: Prosthetic Attachment Screw  
Trade Name: Steri-Oss' Tiodized® Screw  
Classification Name: Endosseous dental implant

Predicate Device:

Substantial equivalence is claimed to Steri-Oss' 1mm and 10mm Coping Screws.

Device Description:

How The Device Functions:

Attachment of prosthetic components to one another and to implants can be achieved with screw fastening systems. The attachment is secured by the application of torque to the screw.

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**510(k) Summary**

**Device Description (continued):**

**Scientific Concepts:**

Screws used to fasten the prosthetic components can sometimes loosen. The greater the preload that is applied, the less chance there is that the screw will eventually become loose. Titanium screws that have been "tiodized®" can be preloaded to a much greater torque than untreated prosthetic component screws and thus are less likely to loosen.

**Characteristics:**

Tiodized® screws are manufactured in diameters (across the head) ranging from 0.086 to 0.106 inches and lengths ranging from 0.160 to 0.576 inches and are composed of titanium alloy that has been subjected to a proprietary anodization process. The screws are slotted or are internally or externally hexed for acceptance of driving tools such as screw drivers, hex drivers and wrenches. Tiodized® screws are provided sterile, and are packaged either individually or in sets of up to 6 screws. Tiodized® screws may also be packaged with dental implants or dental implant prosthetic components.

**Intended Use:**

The intended use for Steri-Oss' tiodized® screws is the screw retained attachment of prosthetic components to one another and to dental implants.

**Comparison to Predicate:**

The following table provides a comparison of the technological characteristics of Steri-Oss' tiodized® screws to the predicate screws.

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**510(k) Summary**

**Device Description (continued):**

**Product Comparison**

Specification/ Characteristic	Predicate: 1mm & 10mm Coping Screws	Steri-Oss' Tiodized® Screw
<b>DESIGN</b>		
Geometry	Threaded Screw	Same
External design (for driver)	Slotted	Slotted, Internally Hexed and Externally Hexed
<b>MATERIAL</b>		
Body material	Titanium alloy	Same
Coating	None	Same
<b>PACKAGING</b>		
Container	Chevron pouch in plastic case	Same
Sterility	Provided Sterile	Same

**Performance Data:**

Not applicable.